

REMARKS/ARGUMENTS

Applicants have included herewith a listing of claims to replace all prior versions. The listing shows the amendments made, and the six new claims which have been added, namely, claims 49-54. Support for the amendments to claim 1, can be found throughout the specification, for example on page 10, lines 15-16; page 27, lines 16-23; and page 58, lines 7-9, and in original claims 29-34. Support for new claims 49-53, can be found throughout the specification, for example, in original claims 29-34. Support for claim 54 can be found throughout the specification, for example, on page 30, lines 29-30. With respect to claims withdrawn from consideration at this time, namely, claims 6-8 and 13-48, Applicants respectfully reserve their right to timely reinstate such claims for further consideration.

Applicants' representatives, Sybil Lombillo and Eugene Moroz gratefully acknowledge the Examiner's time and attention in conducting the telephone interview with them on November 3, 2005. During the interview, the present claim amendments were discussed at length and agreement was reached between the Examiner and Applicants' representatives that the proposed amendments place the case in condition for allowance. Applicants make these amendments for the purpose of facilitating an allowance in this application, and reserve the right to pursue the remaining claims in a continuing application. Pursuant to the Examiner's request, a summary is presented herein of the matters discussed during the teleconference as well as the conclusions and agreements reached.

REJECTION OF CLAIMS UNDER 35 U.S.C. §103(a)

During the telephone conference, Applicants' representatives and the Examiner discussed at length the Examiner's rejection of the claims under 35 U.S.C. §103(a), as being unpatentable over Royer et al., in view of Shuster, and Borchert et al.

Specifically, Applicants explained how claim 1 as amended recites that the transferable reproductive elements are "monoclonal and readily dispersed in suspension", and further that the transformed mutant fungi are cultured under conditions conducive to "formation of the readily dispersible transferable reproductive elements in suspension", enabling separation and transfer of the reproductive elements in the suspension culture. After detailed explanation, the Examiner concurred that none of the references in combination or alone, teaches or suggests

the production of transferable reproductive elements in suspension which are monoclonal and readily dispersed in suspension.

Furthermore, the references cited by the Examiner as explained by Applicants disclose conventional fungal cultures which require multiple steps to mechanically and chemically disrupt fungi in order to release reproductive elements. In Royer, conidia are scraped from plates using a transfer loop, and subsequently passed through several layers of cheesecloth to make conidial suspensions which must then be further disrupted with enzymes to make reproducible elements. (See, Example 8, column 10, lines 40-66). In Borchert, once the fungi have been transformed, it is necessary to prepare spores to separate them (Borchert cites the methods of Unkles et al. (1989) at column 15, lines 51-59). This requires a propagation step (i.e. sporulation) which is done on standard culture dishes or "plates", *not* in suspension. Borchert harvests the spores mechanically from the plates by scraping. Applicants' claimed invention entirely avoids the steps performed in Royer and Borchert, and enables ready separation of the transferable reproductive elements in the suspension culture. This feature makes Applicants' invention amenable to automation, and, as a result, efficient screening of fungally-expressed proteins can now be accomplished. In sum, Royer teaches separation of reproducible elements by mechanical and enzymatic disruption, and Borchert teaches separation by sporulation on solid medium. Neither reference teaches or suggests Applicants' claimed invention.

Furthermore, the Shuster reference does not cure the deficient teachings of Royer and Borchert et al. As discussed previously, Shuster only addresses low-viscosity cultures and their advantages for improved protein production, but does not teach or suggest monoclonal transferable reproductive elements which are readily dispersed in suspension. For this reason, there would have been no motivation to combine the teachings of Shuster with Royer and Borchert because the three references comprise non-overlapping subject matter, with no suggestion on the part of either to utilize their respective teachings to facilitate high-throughput screening.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-5 and 9-12 are rejected under 35 U.S.C. §112, first paragraph, for lack of written description. The Examiner contends that the specification does not provide sufficient written description of a method for a fungal suspension which is characterized by production of

transferable reproductive elements in suspension. In reply, Applicants submit that this rejection is rendered moot by the amendments to the claims. The claims, as amended, recite specific fungal strains which are described in the specification. During the interview, the Examiner agreed that such amendment overcomes the §112 rejection.

With respect to the issue of specification support for Applicants' intention to include the expression of all proteins not only heterologous proteins, Applicants explained that their fungal system contemplated the expression of any protein of interest, even an endogenous overexpressed fungal protein can be produced by the fungal suspension of Applicants' claimed invention. The specification further provides support for the use of homologous, as well as heterologous sequences (see pages 44-49 of the specification).

At the conclusion of the teleconference, the Examiner stated that claim 1 as amended during discussion was in condition for allowance as well as claims dependent thereon.

The remaining rejections were not discussed, in view of the agreement which was reached; however, Applicants briefly address each one below for completeness of their response.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-5 and 9-12 are rejected under 35 U.S.C. §112, second paragraph, for being indefinite. The Examiner contends that the term "low-viscosity" is a relative term that is not defined by the specification.

In response, Applicants have amended the claims to delete the phrase "low-viscosity". Applicants do not intend for the claims to be limited to low-viscosity. In fact, the specification clearly contemplates fungal cultures characterized by greater viscosity (See, page 29, lines 11-13). Accordingly, this rejection is overcome.

REJECTION OF THE CLAIMS FOR DOUBLE PATENTING

Claims 1-5 and 9-12 were rejected for obviousness-type double patenting. The Examiner contends that the claims are already covered by the claims in U.S. Patent No. 6,573,086.

In response, Applicants submit that this rejection is rendered moot by the amendments to the claims. The claims, as amended, are not an obvious variation of the invention claimed in

the '086 patent. For this reason, Applicants respectfully request that the Examiner withdraw the double patenting rejection.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. §102(e)

Claims 1-5 and 9-12 are rejected under 35 U.S.C. §102(e) as anticipated by Emalfarb et al. (WO 00/20555).

In response, Applicants respectfully submit that the cited reference is not an anticipatory reference because 1) no international filing dates prior to November 29, 2000 can be relied upon as prior art under 102(e); 2) the publication date of WO 00/20555 is April 13, 2000, which is the same day that the present application's priority application, PCT/US00/10199 was filed (the priority application also discloses the subject matter currently claimed); and 3) U.S. application No 09/548,938, which is a CIP of WO 00/20555, was also filed on April 13, 2000. For at least these reasons, WO 00/20555 cannot be considered an anticipatory reference under §102.

In view of these remarks, Applicants respectfully request that the Examiner withdraw the §102(e) rejection.

CONCLUSION

In view of the agreement reached between the Examiner and Applicants' representatives, passage to issuance is respectfully requested.

Appl. No. 09/834,434
Amdt. dated Dec. 14, 2005
Reply to Office Action of Sept. 16, 2005

Docket No. 3123-4006

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 3123-4006. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 3123-4006. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
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Dated: December 14, 2005

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